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February 3, 2025

**VIA ECF**

Honorable Julien Xavier Neals, U.S.D.J.  
United States District Court for the District of New Jersey  
Martin Luther King Jr. Bldg. & U.S. Courthouse  
50 Walnut Street  
Newark, New Jersey 07102

**Re: Teva Branded Pharmaceutical Products R&D, Inc. et al., v. Cipla Ltd. et al.**  
**Civil Action No. 2:20-cv-10172 (JXN-MAH) (Consolidated)**

Dear Judge Neals:

This firm represents Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd. in the above captioned matters. We write on behalf of all parties, pursuant to Federal Rule of Civil Procedure 62.1, to seek an "indicative ruling" on a motion under Federal Rule of Civil Procedure 60(b) to modify the injunctive provisions of the Court's Final Judgment Order entered on June 29, 2023 (ECF No. 304), in light of the recent settlement of this action. The parties respectfully request that the Court enter the order attached as Exhibit A.

On February 3, 2025, after full briefing of Defendant Cipla Ltd.'s ("Cipla's") appeal from the final judgment and before oral argument in that appeal, Plaintiffs and Cipla executed a Settlement and License Agreement (the "Agreement") fully resolving, as relevant here, the claims and counterclaims asserted in this action relevant to U.S. Patent Nos. 9,463,289 (the "'289 patent"), 9,808,587 (the "'587 patent"), and 10,561,808 (the "'808 patent") subject to and conditioned upon modification of the Final Judgment Order as described herein. This matter is currently pending on appeal in the United States Court of Appeals for the Federal Circuit (the "Federal Circuit"). Immediately following execution of the Agreement, the parties jointly sought a stay of further appellate proceedings.

The terms of the Agreement are confidential, but as a general matter, the Agreement grants Cipla a license to market the proposed product that is the subject of Cipla's Abbreviated New Drug Application No. 211434 ("Cipla's ANDA Product") on a specified date before the expiration of the '289 patent, the '587 patent, and the '808 patent. The parties also agreed to approach this Court seeking a modification of certain provisions of the Final Judgment Order. Specifically, the parties respectfully request that the Court modify the Final Judgment Order (ECF No. 304), which enjoins Cipla from, among other things, selling or offering for sale Cipla's ANDA Product until expiration of the '289 patent, the '587 patent, and the '808 patent, to allow Cipla to engage in such activities pursuant to the terms of the Agreement. The Final Judgment Order and its underlying findings and conclusions of law would otherwise remain intact. Amending the Final Judgment Order in this manner is necessary for Cipla to exercise its license rights under the Agreement and is an express condition of the Agreement's continued effect.

Specifically, to give practical effect to the terms of the Agreement, Cipla must be free to market Cipla's ANDA Product consistent with the terms of the Agreement, and the U.S. Food and Drug Administration ("FDA") must be free to approve Cipla's ANDA Product. Effectuation of the parties' agreement, therefore, requires that the Final Judgment Order be modified to amend the injunction entered against Cipla, which, *inter alia*, enjoins Cipla from manufacturing and selling Cipla's ANDA Product during the term of the '289 patent, the '587 patent, and the '808 patent. It further requires that the Final Judgment Order be modified to allow the FDA to approve Cipla's ANDA Product prior to the expiration patents. A copy of the parties' proposed Modified Final Judgment Order is attached as Exhibit B (redline over ECF No. 304 as Exhibit C).

Pursuant to Federal Rule of Civil Procedure 62.1, a district court, while divested of jurisdiction by a pending appeal, *see, e.g.*, *Venen v. Sweet*, 758 F.2d 117, 120 (3d Cir. 1985), may nonetheless provide an "indicative ruling" stating that it would grant a motion under Federal Rule of Civil Procedure 60(b) if the appellate court remands for that purpose pursuant to Federal Rule of Appellate Procedure 12.1. Such an "indicative ruling"—to the effect that this Court would modify its Final Judgment Order to amend the injunctive relief provisions if the Federal Circuit should remand this case—is the precise relief the parties seek here; it is also the very type of relief for which Federal Rule of Civil Procedure 62.1 was enacted. See FED. R. CIV. P. 62.1, 2009 Advisory Committee Note. In similar Hatch-Waxman cases, this Court has granted such "indicative rulings" that it would modify the injunctive relief set forth in a final judgment in order to effectuate a settlement agreement reached between the parties during a pending appeal. See *Janssen Prods., L.P. v. Lupin Ltd.*, No. 10-cv-5954 (WHW), 2016 WL 3392291, at \* 4 (D.N.J. June 15, 2016).<sup>1</sup> If this Court grants this Motion, the parties would then notify the Federal Circuit pursuant to Federal Rule of Appellate Procedure 12.1 and request that the Federal Circuit remand this action for entry by the Court of a modified Final Judgment Order.

The parties thus respectfully request that the Court issue an Indicative Ruling pursuant to Federal Rule of Civil Procedure 62.1 stating that the Court would enter an order modifying the Final Judgment Order and amending the injunctive relief provisions to allow permitted activities under the Agreement, including the FDA approval, manufacture, and sale of Cipla's ANDA Product prior to the expiration of the '289 patent, the '587 patent, and the '808 patent, were the Federal Circuit to remand the case for this purpose. If and when the Court issues the requested ruling, the parties will jointly request that the Federal Circuit remand the case to this Court to allow for modification of the Final Judgment Order. In the event that the Court refrains from entering an Indicative Ruling of the nature described herein, the parties' Agreement will not take effect and the parties will proceed with the currently pending appeal.

If your honor agrees, the parties respectfully request that the attached Order be entered as soon as possible. We thank the Court for its continued attention to this matter and are available if Your Honor or Your Honor's staff requires anything further.

Respectfully submitted,

/s/ *Liza M. Walsh*

Liza M. Walsh

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<sup>1</sup> *See also Janssen Prods., L.P. v. Lupin Ltd.*, No. 10-CV-5954 (WHW) (D.N.J. June 21, 2016), ECF No. 1075 (entering proposed modified order on remand).